APR 2 2 2011

510(k) Summary: AVS® Anchor-C Cervical Cage System	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Kimberly Lane Sr. Regulatory Affairs Specialist Phone: 201-760-8215 Fax: 201-760-8415 Email: kimberly.lane@stryker.com
Date Prepared	April 19, 2011
Trade Name	AVS® Anchor-C Cervical Cage System
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR 888.3080
Product Code	ODP
Predicate Devices	The AVS® Anchor-C Cervical Cage System was shown to be substantially equivalent to the devices listed below: • LDR *MC*+, 510(k) # K091088 • Surgicraft *STALIF C*, 510(k) #K072415 • Depuy *Bengal* #K081917 • Spinal Elements *Crystal* #K073351 • Zimmer *BAK/C* # P980048 • Medtronic *AFFINITY* #P000028
Device Description	The AVS® Anchor-C Cervical Cage is a hollow, rectangular-shaped PEEK Optima® LT1 (per ASTM F2026) cage assembled to a titanium alloy Ti6Al4V (per ASTM F136 and ISO 5832-3) plate and has one tantalum marker (per ASTM F560). It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to adapt to varying patient anatomies. The PEEK Optima® LT1 cage

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	portion consists of one closed pocket for graft containment and has serrations on the superior and inferior surfaces of the cage. The implant is designed to be used exclusively with the internal supplemental fixation provided (AVS® Anchor-C Fixation Screws). The AVS® Anchor-C Fixation Screws are constructed from titanium alloy Ti6Al4V (per ASTM F136 and ISO 5832-3) and possess clips (also constructed from titanium alloy Ti6Al4V per ASTM F136 and ISO 5832-3) that mate with internal features located within the AVS® Anchor-C Cervical Cage. Once fully seated into the holes, the screws are designed to lock into the titanium plate.
Intended Use	The Stryker Spine AVS® Anchor-C Cervical Cage System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The AVS® Anchor-C Cervical Cage is to be used with autogenous bone graft and implanted via an open, anterior approach. The AVS® Anchor-C Cervical Cage must be used with the internal screw fixation provided by AVS® Anchor-C Fixation Screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment.
Summary of the Technological Characteristics	The subject AVS® Anchor-C implant system and the predicates share similar design features: • Graft windows for packing autogenous bone

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	• Serrations on the superior and inferior surfaces • Comparable heights, widths, depths, and lordotic angles Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® Anchor-C implant system and demonstrated substantially equivalent performance to the identified predicate device systems. The following mechanical tests were performed: • Static Compression (per ASTM F2077) • Dynamic Compression (per ASTM F2077) • Static Compression Shear (per ASTM F2077) • Dynamic Compression Shear (per ASTM F2077) • Static Torsion (per ASTM F2077) • Dynamic Torsion (per ASTM F2077) • Expulsion (per ASTM F04-25-02-02 Draft) • Subsidence (per ASTM F2267)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Spine
% Ms. Kimberly Lane
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

SEP

Re: K102606
Trade/Device Name: Stryker Spine AVS® Anchor-C Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: April 4, 2011
Received: April 5, 2011

Dear Ms. Lane:

This letter corrects our substantially equivalent letter of April 22, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K K102606

Device Name: Stryker Spine AVS® Anchor-C Cervical Cage System

Indications For Use:

The Stryker Spine AVS® Anchor-C Cervical Cage System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The AVS® Anchor-C Cervical Cage is to be used with autogenous bone graft and implanted via an open, anterior approach.

The AVS® Anchor-C Cervical Cage must be used with the internal screw fixation provided by AVS® Anchor-C Fixation Screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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